



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 14 and 1120

[Docket No. FDA-2013-N-0227]

Proposed Requirements for Tobacco Products Manufacturing Practice; Tobacco Products Scientific Advisory Committee; Notice of Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (TPSAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues related to tobacco products. This meeting will be held to discuss and provide an opportunity for recommendations on the Requirements for Tobacco Product Manufacturing Practice (TPMP) proposed rule. The meeting will be open to the public.

DATES: The meeting will be held on May 18, 2023, from 9 a.m. to 2 p.m. Eastern Time.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993-0002. For those unable to attend in person, the meeting will also be webcast and will be available at the following link:

<https://fda.zoomgov.com/j/1600966352?pwd=bmRrRlp1MlUrdWVmR095KzN3eWV1UT09;>

Passcode: Y=Sw4a. Answers to commonly asked questions including information regarding special accommodations due to disability, visitor parking, and transportation may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA has established a docket for public comment (Docket No. FDA-2013-N-0227).

Please note that late, untimely filed comments will not be considered by the committee. Either electronic or written comments on this public advisory committee meeting must be submitted by

May 11, 2023, for consideration by the committee. The <https://www.regulations.gov> electronic filing system will accept comments on this public advisory committee meeting until 11:59 p.m. Eastern Time at the end of May 11, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before May 11, 2023, will be provided to the committee and become part of the docket. Comments received after May 11, 2023, and prior to [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], will also become part of the docket, but will not be considered by the committee. In the event that the meeting is canceled, FDA will continue to evaluate any relevant information and consider any comments submitted to the docket for the TPSAC meeting, as appropriate. FDA also reminds the public that commenters may submit either electronic or written comments on the proposed rule published elsewhere in this issue of the *Federal Register* by [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in

the body of your comments, that information will be posted on

<https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2013-N-0227 and “Proposed Requirements for Tobacco Products Manufacturing Practice; Tobacco Products Scientific Advisory Committee; Notice of Meeting; Request for Comments.”

Comments on this public advisory committee meeting (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Eastern Time, Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you identify as confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” FDA will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 1-877-287-1373, TPSAC@fda.hhs.gov; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA’s website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On May 18, 2023, the committee will meet in open session to discuss and provide recommendations on the TPMP proposed rule (proposed 21 CFR part 1120), published elsewhere in this issue of the *Federal Register*.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm> and can be accessed by scrolling down to the appropriate advisory committee meeting link.

Procedure: On May 18, 2023, from 9 a.m. to 2 p.m. Eastern Time, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see ADDRESSES) on or before May 11, 2023, will be provided to the committee. In the event that the meeting is canceled, FDA will continue to evaluate any relevant information and consider any comments submitted to the docket for the TPSAC meeting, as appropriate. FDA also reminds the public that commenters may submit either electronic or written comments on the proposed rule by [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Oral presentations from the public will be scheduled between approximately 9:30 a.m. to 10:30 a.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with their names, email addresses, and direct contact phone numbers of proposed participants, on or before 12 p.m. Eastern Time on May 3, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open

public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by 6 p.m., May 4, 2023.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at TPSAC@fda.hhs.gov (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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